

## BioVentrix Names Vinod H. Thourani, MD and Marat Fudim, MD, MHS as National Co-Principal Investigators for RELIVE Trial

Renowned Cardiologists to Lead Pivotal Trial Evaluating the BioVentrix Revivent System for Heart Failure Patients

MANSFIELD, MA, UNITED STATES, August 27, 2025 /EINPresswire.com/ --BioVentrix, Inc., a medical device company focused on developing innovative therapies to restore heart



function, today announced the appointment of Vinod H. Thourani, MD, and Marat Fudim, MD, MHS, as national co-principal investigators for the company's pivotal RELIVE clinical trial.

The RELIVE trial will study the safety and efficacy of BioVentrix's proprietary Revivent System in



Dr. Thourani & Dr. Fudim bring world-class surgical and clinical research expertise to the RELIVE trial. They will ensure the trial is conducted with scientific rigor and ethical integrity." Steve Chartier, President & Co-CEO, BioVentrix, Inc.

restoring left ventricular function in heart failure patients with reduced ejection fraction and extensive left ventricular scarring. The minimally invasive Revivent System has previously received Breakthrough Therapy Designation by the U.S. Food and Drug Administration.

Dr. Thourani is a leading cardiothoracic surgeon specializing in minimally invasive and transcatheter aortic and mitral valve therapies. He serves as Chair of the Department of Cardiac Surgery at Piedmont Heart Institute in Atlanta, GA, and has held leadership roles in cardiothoracic surgery including President of the Southern

Thoracic Surgical Association and President-elect of the Heart Valve Society.

Dr. Fudim is Associate Professor of Medicine (Cardiology) at Duke University and Medical Director of the Heart Failure Research Unit at the Duke Clinical Research Institute. He is an internationally recognized expert in advanced heart failure, mechanical assist devices, and novel hemodynamic therapies.

In a joint statement, Dr. Thourani and Dr. Fudim said: "Heart attacks can lead to scarring and remodeling of heart tissue, which may compromise the heart's ability to pump effectively and increase the risk of heart failure—a condition that poses serious health challenges. In the United States, an estimated 28,000 patients each year develop large anterior scars following a heart attack, potentially qualifying them for investigational treatments like the Revivent procedure. The RELIVE trial aims to assess the Revivent System's external anchor surgical approach across a broader patient population and evaluate multiple clinical outcomes."

The RELIVE (Randomized Evaluation of Less Invasive Ventricular Enhancement) Trial is a prospective, randomized, multi-center, dual-arm pivotal study of the BioVentrix Revivent System. Enrollment in the RELIVE Trial is expected to begin in the second half of 2025 and will involve 90 treated and 45 control patients.

"Dr. Thourani and Dr. Fudim bring world-class surgical and clinical research expertise to the RELIVE trial," said Steve Chartier, President and Co-Chief Executive Officer of BioVentrix. "Their leadership—shaped by decades of pioneering work in cardiovascular innovation—will ensure the trial is conducted with scientific rigor, ethical integrity, and an unwavering commitment to improving patient outcomes."

## About the Revivent System

The BioVentrix Revivent System is designed to support a minimally invasive procedure to treat a dilated left ventricle of patients with ischemic heart failure with reduced ejection fraction (HFrEF) and extensive left ventricular scar, who have a suboptimal response to guideline-directed medical therapy. The procedure uses myocardial micro-anchor implants to reconstruct the dilated left ventricle to produce a more efficient chamber. Prior trials showed statistical significance with a subpopulation for similar endpoints to those that will be assessed in the RELIVE Trial. The Revivent System received the CE Mark in 2016.

## **About BioVentrix**

BioVentrix, Inc. is a medical device company focused on developing innovative therapies to restore heart function and enhance the quality of life for patients suffering from advanced heart failure. Its solutions offer heart failure specialists new treatment options aimed at improving left ventricular function which may increase cardiac ejection fraction. The company's flagship product, the Revivent System, is currently undergoing evaluation in the RELIVE Study, a pivotal clinical trial in the United States, and is in the early stages of commercialization across Europe.

The BioVentrix trademark is a federally registered trademark owned by BioVentrix. Any unauthorized use is expressly prohibited.

Investigational Device. The Revivent System is limited to Investigational Use Only in The United States.

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